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Short-Term Safety and Efficacy of Transvaginal Prolapse and Incontinence Repairs with a Novel Acellular Dermal Allograft Using Graft-Only Tissue Technique

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Abstract

Introduction: In the wake of the removal of transvaginal mesh a durable and functionally successful transvaginal method for pelvic organ prolapse repair is needed. This study evaluates a new technique using a novel acellular dermal graft without the need to plicate tissue.

Objective: Determine safety and efficacy of transvaginal pelvic organ prolapse and stress incontinence repair employing a novel acellular dermal allograft.

Materials and Methods: This was a non-probability consecutive retrospective review of patients receiving anterior-apical and/or posterior-apical repair, uterine suspension, and sling with novel allograft graft (AllomendTM, Allosource, Denver, CO, USA) from October 2021 and March 2022. The patients were followed to 3-months post-operative. Surgical technique for apical, uterine, anterior, posterior repair involved proprietary graft design and implantation technique without native tissue repair using modified sacrospinous fixation. Demographics, intraoperative complications, adverse events (AE's) recorded, as was urinary, bowel and sexual symptoms were measured by subjective report and QOL measures (FSFI, UDI-6, IIQ-7). Anatomic efficacy was determined by Pelvic Organ Prolapse Quantification System (POP-Q).

Results: 54 patients were implanted. Mean age 55.6 and median parity 2.0. Procedures performed; vault suspension (43), uterine suspension (29), anterior repair (41), posterior repair (31), sling (20). No intraoperative complications reported. Follow-up obtained at 2-weeks (n = 54), 6-weeks (n = 43), 3-months (n = 28). AE's included 7 patients with UTIs at 2 and 6 weeks, 1 with dysuria at 2-weeks and 3 with fecal incontinence or urgency at 2 and 6-weeks. Baseline prolapse anatomy for areas repaired included median POP-Q values of stage (3), C (-4), D (-5), Aa (0), Ba (0), Ap (0), Bp (0). Median values at both 6-weeks and 3-months were stage (0), C (-10), D (-11), Aa (-3), Ba (-3), Ap (-3), Bp (-3) [all $p < 0.001$]. At baseline, urge incontinence symptoms present in 49 (91%), stress 51 (94%), mixed 48 (89%). At 3-months there were 2 cases of persistent urge (7%), no persistent stress or mixed symptoms ($p < 0.001$). Baseline 28 (52%) of patients were sexually active 20 (71%) reporting dyspareunia. At 3-months 18 (64%) of patients were sexually active with no dyspareunia reported ($p < 0.001$). Mean UDI-6 values at baseline (n = 54) were 59.46 (± 14.34), 1.72 (± 3.45) at 6-weeks (n = 43, $p < 0.001$) and 2.32 (± 3.62) at 3-months (n = 28, $p < 0.001$). Mean IIQ-7 values at baseline (n = 54) were 82.07 (± 15.79), 4.63 (± 10.14) at 6-weeks (n = 43, $p < 0.001$) and 3.96 (± 8.41) at 3-months (n = 28, $p < 0.001$). Mean FSFI values at baseline (n = 54) were 26.36 (± 6.98) and 31.31 (± 2.57) at 3-months (n = 28, $p < 0.001$). No anatomic failures, graft exposures or healing abnormalities reported.

Keywords: *Transvaginal Prolapse; Incontinence Repairs; Novel Acellular Dermal Allograft; Graft-Only Tissue Technique*

Introduction

Pelvic organ prolapse and stress urinary incontinence are common conditions impairing women's quality of life post-child bearing. One in 3 suffer from significant incontinence and 50% of women experience at least a stage 2 prolapse during their lifetime [1,2]. Annually over 300,000 incontinence procedures and 200,000 prolapse procedures are performed in the United States [3]. A transvaginal surgical approach continues to be the least invasive female pelvic reconstructive option and is the recommended primary choice by the American College of Obstetrics and Gynecology [4]. Native tissue repairs with a plication technique are the primary technique for transvaginal repairs. However, native tissue plication is associated with numerous shortcomings including a failure rate in excess of 50% [5] and significant functional impairment with reported high rates of dyspareunia and bowel and bladder dysfunction [6]. Transvaginal synthetic mesh repairs were introduced in the early 2000s in an effort to improve anatomic outcomes, however, due to reported complication rates and legal pressure are no longer available for use [7]. This has left few viable transvaginal surgical options available for women suffering from these conditions. Due to the lack of transvaginal options many surgeons have reverted to open abdominal, laparoscopic, or robotic approaches. These approaches are associated with longer operating times, increased morbidity and mortality and a higher level of complexity. Thus, the reintroduction of a durable and highly functional vaginal approach repair without the risks associated with transvaginal mesh is of critical importance. The study reports on a proprietary, patent-pending implantation non-plication technique using an acellular dermal graft with a specific design to allow for a transvaginal repair using biologic tissue without the shortcomings of native tissue repairs.

Objective of the Study

To retrospectively evaluate the short-term anatomic and functional outcomes of a novel non-plication technique for the correction of pelvic organ prolapse and female stress urinary incontinence using an acellular dermal graft.

Materials and Methods

IRB exemption was obtained. A retrospective review of patients receiving anterior-apical and/or posterior-apical repair, uterine suspension, and/or a mid-urethral sling with the proprietary technique and novel graft between October 2021 and March 2022 was performed. The allograft is acellular human dermal graft (Allomend™, Allosource, Denver, CO, USA) processed using a patented decellularization technology allowing low immunologic response [8] while retaining growth factors and collagen structure for strength, ingrowth, and angiogenesis [9].

Demographics recorded included age and parity. Intraoperative complications, adverse events (AE's) were recorded. Outcomes measured included urinary, bowel and sexual symptoms measured by subjective report and validated QOL measures the Female Sexual Function Index (FSFI), Urogenital Distress Inventory-short form (UDI-6), and Incontinence Impact Questionnaire-short form (IIQ-7). Anatomic efficacy was determined using the Pelvic Organ Prolapse Quantification System (POP-Q). Data were recorded at baseline, 2-weeks post-operative, 6-weeks post-operative and 3-months post-operative.

Surgical technique for apical, uterine, anterior, and posterior vaginal repairs involved proprietary graft design and implantation without involvement of a native tissue repair using a modified bilateral sacrospinous fixation technique. A unique non-suture anchoring system to allow direct fixation of the dermal graft into the sacrospinous ligaments and Arcus Tendineus Fascia Pelvis (ATFP) was used. The technique for a stress incontinence repair involved a 'top-down' retropubic approach with a shaped sling design and fixation over the rectus fascia.

This was a non-probability consecutive retrospective review to 3-months post-operative of all subjects in which this technique was utilized in the above time period. Summary statistics are presented as mean (SD) or Median (IQR) for continuous variables, and count

(%) for categorical variables. Wilcoxon ranked sum tests (paired) were used due to non-normal distribution for continuous variables. For categorical variables, baseline proportions with 95% confidence interval (CI) were calculated and compared to the point estimated proportion at other time points. A percentage outside of the 95% CI indicates statistical significance.

Results

54 patients were implanted with the novel graft in the 6-month period. Mean subject age was 55.6 years and median parity was 2.0. Most subjects had multiple concomitant procedures performed. Procedures performed were vault suspension (n = 43), uterine suspension (n = 29), anterior repair (n = 41), posterior repair (n = 31), sling (n = 20). No intraoperative complications were reported. Follow-up was obtained at 2-weeks (n = 54), 6-weeks (n = 43), 3-months (n = 28). AE's reported included 7 patients with UTIs at 2 and 6 weeks, 1 with dysuria at 2-weeks and 3 with transient fecal incontinence or urgency at 2 and 6-weeks. Baseline prolapse anatomy for areas repaired included median POP-Q values of stage (3), C (-4), D (-5), Aa (0), Ba (0), Ap (0), Bp (0). Median values at both 6-weeks and 3-months were stage (0), C (-10), D (-11), Aa (-3), Ba (-3), Ap (-3), Bp (-3) [$p < 0.001$ at all data points]. At baseline, urge incontinence symptoms were subjectively reported in 49 (91%) subjects, stress incontinence symptoms were present in 51 (94%) subjects, and mixed incontinence in 48 (89%) of subjects. At 3-months there were 2 cases (7%) of persistent subjective urge incontinence ($p < 0.001$). No persistent stress or mixed symptoms ($p < 0.001$) were reported. At baseline 28 (52%) of patients were sexually active 20 (71%) reporting dyspareunia. At 3-months 18 (64%) of patients were sexually active with no dyspareunia reported ($p < 0.001$). Mean UDI-6 values at baseline (n = 54) were 59.46 (± 14.34), 1.72 (± 3.45) at 6-weeks (n = 43, $p < 0.001$) and 2.32 (± 3.62) at 3-months (n = 28, $p < 0.001$). Mean IIQ-7 values at baseline (n = 54) were 82.07 (± 15.79), 4.63 (± 10.14) at 6-weeks (n = 43, $p < 0.001$) and 3.96 (± 8.41) at 3-months (n = 28, $p < 0.001$). Mean FSFI values at baseline (n = 54) were 26.36 (± 6.98) and 31.31 (± 2.57) at 3-months (n = 28, $p < 0.001$). No anatomic failures, graft exposures or healing abnormalities occurred.

Discussion

A transvaginal approach for a POP repair remains the option of choice for most women needing surgical intervention. This is supported by the American College of Obstetrics and Gynecology as well as many other influential women's pelvic surgery societies. The utility of a vaginal approach has been limited, however, by poor anatomic and functional outcomes. Prior studies utilizing biologic grafts, without the holding strength or healing characteristics of this novel graft, placed or attached as a patch have not shown a clear advantage over native a tissue repair [10,11]. Transvaginal mesh was introduced in an attempt to match the benefits of a minimally invasive vaginal approach with the durability of a synthetic graft, but complications and medicolegal pressure forced its removal. The loss of this option created a vacuum of surgical choices for POP repair. Consequently, many more women are going uncared for and there has been a shift in technique toward open abdominal, laparoscopic or robotic procedures that carry a higher operative time, increased morbidity and mortality, increased cost, and higher complexity. The lack of current options is of even more acute importance in countries without the ready availability of advanced laparoscopic or robotic equipment. Developing a transvaginal procedure that has healing risks similar to native tissue repairs with the durability of mesh repairs is, therefore, critical to improve POP surgical results.

This study evaluated the outcomes of transvaginal POP and incontinence repairs with a novel acellular graft using a proprietary, patent-pending technique. The graft, for POP repairs, is designed to attach to the vaginal apex and/or cervix and covers the entire compartment requiring repair. Further, it is designed to extend to the sacrospinous ligaments and other ligamentous attachments with anchors into these structures at all stress points.

The results of this 3-month retrospective study are promising. There were no significant intra-operative or post-operative AE's reported and no wound healing issues of any type in the entire series. In addition, there were no short-term anatomic failures, with POP-Q scores demonstrating normal anatomy in all post-op subjects at all examination points. Improvement in bladder, bowel and sexual function were all significant with UDI-6, IIQ-7 and FSFI scores all showing significant improvement ($p < 0.001$).

This study provides promising preliminary data in the development of a procedure that may match the durability of a synthetic graft procedure with the healing risks consistent with a native tissue repair and superior functional results. Limitations were the single-arm retrospective design and length of follow-up. This proprietary, patent-pending technique in combination with the novel graft (Allomend™) may offer women a legitimate solution to many of the shortcomings of current surgical options for POP.

Conclusion

These proprietary transvaginal prolapse and anti-incontinence techniques were found to be safe and effective in the short-term utilizing a novel acellular dermal graft (Allomend™) without the need to involve a native tissue repair. A longer follow-up period and prospective, comparative studies are needed to further evaluate outcomes.

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